

Facts You Need to Know About Custom-Contoured Ablation Patterns (Custom-CAP™ Method) for the Treatment of Patients with Decentered Ablations from Previous Laser Surgery

Patient Information Booklet

CAUTION: HUMANITARIAN DEVICE. Authorized by U.S. Federal Law for use in the treatment of symptomatic decentered ablations from previous laser surgery. The effectiveness of this device for this use has not been demonstrated.

Please read this entire booklet. Discuss its contents with your doctor so that all your questions are answered to your satisfaction. Ask any questions you may have before you agree to the surgery.

VISX, Incorporated
3400 Central Expressway
Santa Clara, CA 95051-0703
U.S.A.

Tel: 408.733.2020

© Copyright 2002 by VISX, Incorporated

All Rights Reserved

VISX® is a registered trademark of VISX, Incorporated.

STAR S3 ActiveTrak™ is a trademark of VISX, Incorporated.

Custom-CAP™ Method is a trademark of VISX, Incorporated.

VisionKey® is a registered trademark of VISX, Incorporated.

The VISX Reader/Writer utilizes software owned by Bull Worldwide Information Systems.

No part of this publication may be reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopying, recording, or any information storage and retrieval system, without permission in writing from VISX, Incorporated.

Table of Contents

Introduction.....	1
Device Description.....	1
How the Eye Functions.....	2
What are PRK and LASIK?	2
What is Custom-CAP™	3
Benefits.....	3
Risks.....	4
The First Week Following Surgery.....	4
The First Two To Six Months Following Surgery	4
One or More Years After Surgery.....	4
Contraindications	4
Warnings	5
Precautions.....	5
Before the Surgery	6
The Day of Surgery	6
After Surgery	8
Questions to Ask Your Doctor.....	9
Self-Test	10
Summary of Important Information	11
Answers to Self-Test Questions:.....	12
Glossary	13

CAUTION: HUMANITARIAN DEVICE. Authorized by U.S. Federal Law for use in the treatment of symptomatic decentered ablations from previous laser surgery. The effectiveness of this device for this use has not been demonstrated.

Introduction

The information in this booklet is to help you decide whether to have laser surgery to correct or partly correct your decentered treatment from your previous laser refractive surgery. Another way to correct your decentered treatment and the problems that you have experienced since then is with a corneal transplant.

If both of your eyes are suffering from decentered laser treatments that cause you to see poorly, with ghosts, glare, or other visual disturbances, you might be a candidate for the surgery in both eyes. Because of the complicated nature of this surgery, it is advisable but not necessary, to do the surgery on one eye at a time. Talk with your doctor about whether it would be better to treat one or both of your eyes.

Please read this booklet completely. Discuss any questions with your doctor before you decide if this treatment is right for you. Only an eye care professional trained in laser surgery with the Custom-CAP™ Method can determine whether you are a suitable candidate.

Device Description

The STAR S3 ActiveTrak™ Excimer Laser System comprises hardware components that enable accurate results for patients undergoing laser vision correction. Vision corrections are generated by programming patient vision data into the laser's established software program to provide for appropriate vision correction.

How the Eye Functions

The cornea and lens of the eye focus light like a camera lens to form an image on the retina at the back of the eye. The cornea, where light first enters the front of the eye, provides about two thirds of the eye's focusing power, and the lens inside the eye provides the other third. After you have had laser refractive surgery that has been or that has become decentered (caused either by unintentional surgical decentration or asymmetrical healing), the image on the retina is blurred.

During a regular eye examination, your doctor uses lenses to measure your prescription in units called *diopters*. In addition, your doctor uses a corneal mapping or topography system to determine how well centered the procedure is or has become with healing.

What are PRK and LASIK?

PRK is laser surgery to correct nearsightedness (myopia), farsightedness (hyperopia), and astigmatism. For nearsightedness with or without astigmatism, an excimer laser beam is used to flatten the front of the cornea. The laser beam removes small amounts of tissue from the front of the cornea. For farsightedness with or without astigmatism, the excimer laser beam is used to steepen the front of the cornea. To do this, the laser beam removes small amounts of tissue from a ring-shaped area around the center of the cornea.

LASIK is similar to PRK, but does not treat or alter the front surface of the cornea. The doctor uses an instrument called a *microkeratome* to create a circular flap of corneal tissue. The flap is then lifted from the cornea while the doctor uses the excimer laser to remove small amounts of underlying tissue from the exposed cornea. The corneal flap is then repositioned.

An excimer laser produces a powerful beam of ultraviolet light. The laser is controlled by the doctor. It produces a series of rapid pulses that removes small amounts of corneal tissue. Excimer laser light does not penetrate the eye and leaves other eye structures (iris, lens, retina) undisturbed. PRK and LASIK differ from RK, which uses a knife to make deep cuts around the center of the cornea.

Although their vision without glasses improved, some patients still needed glasses or contact lenses after laser refractive surgery. However, when the initial treatment is decentered, typical signs or symptoms include visual disturbances such as glare, ghosts, and halos. Glasses and contact lenses may help somewhat or not at all with the symptoms of ghosting and glare. Sometimes one might experience double vision.

VISX has worked with one topography unit manufacturer to develop planning software that will allow doctors to simulate corrective surgical results on a computer. This information can then be integrated with the STAR S3 ActiveTrak™ Excimer Laser System to create a pattern of laser treatment that could make your vision better and the treatment more centered relative to your pupil and line of sight.

What is Custom-CAP™

Custom-CAP is a procedure (either PRK or LASIK) that is performed on patients who have already had at least one previous laser refractive procedure and have had a treatment that is not well centered relative to the patient's pupil and line of sight. The procedure is meant to be performed on patients who have these decentered treatments and who complain of ghosts, doubling of images, and glare.

Benefits

- Correcting the symptoms of glare, ghosts, and halos associated with a decentered laser vision procedure.
- Improving vision either with or without corrective lenses.

Risks

As with any surgical procedure there are risks associated with laser vision correction. It is important to discuss these risks with your doctor before you make the decision to have the surgery. If the results of the surgery are not satisfactory, you may need to have additional surgery in the same eye. The use of the Custom-CAP™ Method could result in worsened vision, corneal scarring, corneal irregularities, and could cause a cornea to be thinned so much that it may be necessary to have corneal transplant surgery. There may be other risks that cannot be foreseen.

The First Week Following Surgery

- Pain and discomfort may last for up to 3 days after surgery.
- Blurred vision and tearing will occur as the cornea heals.
- You will be sensitive to bright lights.

The First Two To Six Months Following Surgery

- Your intraocular pressure may increase due to use of anti-inflammatory medications. This is usually resolved by drug therapy or by stopping the anti-inflammatory medication.
- Your cornea may become hazy or cloudy enough to affect your vision. This haze typically disappears over time, but some patients may continue to experience haze.

One or More Years After Surgery

Some patients report visual complaints at one or more years after surgery.

Contraindications

You should **NOT** have laser surgery using the Custom-CAP Method if:

- You have collagen vascular, autoimmune, or immunodeficiency diseases (for example, lupus or AIDS).
- You are pregnant or nursing.
- You show signs of keratoconus (corneal disease with a thin cornea).

- You are taking one or both of the following medications:
 - Accutane* (isotretinoin).
 - Cordarone† (amiodarone hydrochloride).

Warnings

- The Custom-CAP™ Method has not been validated for the treatment of corneas with decentered ablations.
- The Custom-CAP Method may produce a decrease in vision and/or increase in corneal irregularity.
- The Custom-CAP Method should not be used on eyes with keratoconus or suspected keratoconus.
- The Custom-CAP Method may increase the likelihood of additional corrective surgery.

Discuss with your doctor if:

- Your prescription is still changing.
- You are diabetic or have severe allergies.
- You have a history of *Herpes simplex* or *Herpes zoster* of the eye.

Precautions

The safety and effectiveness of the STAR S3 ActiveTrak™ Excimer Laser System have **NOT** been established:

- In eyes with corneal disease or abnormality (for example, scar, infection, etc.).
- In eyes with previous surgery or injury to the center of the cornea where the surgery will be performed.
- In eyes with progressive nearsightedness, astigmatism, or farsightedness.
- In eyes with abnormal blood vessels within 1.0 mm of the cornea area where PRK or LASIK will be performed.

* Accutane is a registered trademark of Hoffman-La Roche Inc.

† Cordarone is a registered trademark of Sanofi.

- In patients who are taking sumatriptan (Imitrex*) for migraine.
- In patients who have a tendency to form scars.
- In patients taking hormone replacement therapy or antihistamines who may experience delayed re-epithelialization of the cornea following surgery.
- In patients who have had prior incisional refractive surgery.

Before the Surgery

You will need to have a pre-surgical examination to determine if your eye is healthy and suitable for Custom-CAP™ treatment. This will include a complete physical and eye history, and thorough examination of both eyes. In addition, computerized mapping of your cornea will be done to determine the required correction for the Custom-CAP treatment.

WARNING:

If you wear contact lenses, it is very important to stop wearing them 2 – 4 weeks before examination and treatment for the doctor to obtain a stable eye measurement. Failure to do this might produce suboptimal surgical results.

Before the surgery, please tell your doctor whether you take any medications or have any allergies. Also, talk with your doctor about eating or drinking immediately before the surgery. You should also arrange for transportation, since you must not drive immediately after the surgery. You may resume driving only after receiving permission from your doctor.

The Day of Surgery

Before the surgery you will be asked to listen to the sounds of the treatment so that you will be prepared for the noise the laser makes during surgery. Anesthetic (numbing) drops will be placed into the eye to be treated and you will be escorted into the room with the laser. You will

* Imitrex is a registered trademark of Glaxo Group Ltd.

lie on your back in a reclining chair and look up. An instrument will be placed between your eyelids to hold them open during the surgery. There will also be a temporary shield covering the eye not having surgery.

The PRK surgery begins with removal of the epithelium, the top layer of the cornea. This is done either with the laser or with a small spatula.

The LASIK surgery begins with the placement of a suction ring which elevates the pressure in the eye. The vision in the eye will go black as the suction increases the pressure in the eye. The movement of the microkeratome in the track of the suction ring cuts a circular corneal flap. This flap of tissue will be lifted by the doctor after the suction is released. Vision will return to the eye after the suction is released. Once surgery is complete, the flap will be folded back into place.

For both PRK and LASIK surgery, the doctor will then reposition your head in the chair and refocus the microscope. You will be asked to look directly at a blinking red light. Try to keep both eyes open without squinting, as this makes it easier to keep looking at the blinking red light. Small amounts of tissue will then be removed from your cornea using the STAR S3 ActiveTrak™ Excimer Laser System.

PRECAUTION:

It is very important that you keep looking at the blinking red light during the procedure, even if the light fades or becomes dim. You need to concentrate on looking at this red, blinking light throughout the treatment to prevent the laser vision correction from being off target.

Typically, the laser beam will be applied to your eye less than 1 minute and, overall, the surgery may last about 10 minutes.

After the laser surgery is complete, some eye drops may be placed on your eye. The surgery is painless because of the anesthetic drops. If PRK surgery was performed, a bandage contact lens or a patch may be placed on your eye.

When the anesthetic drops wear off (about 45 to 60 minutes), your eye may hurt for 1 to 3 days if PRK surgery was performed. Most patients describe this pain as moderate to severe. In LASIK surgery, the discomfort is less severe, typically described as “a sandy sensation.” Your doctor can prescribe pain medication to make you more comfortable during this time after the surgery. To promote healing and to lessen the risk of infection, do **NOT** rub your eyes for the first 3 to 5 **days** after PRK surgery and for 3 to 5 **months** after LASIK surgery.

IMPORTANT:

Your doctor will monitor you for any side effects if topical steroids were used. Possible side effects of prolonged topical steroid use are ocular hypertension, glaucoma, or cataract formation.

After Surgery

You will be mildly sensitive to light and have the feeling that something is in your eye for the first few days. Sunglasses may make you more comfortable during this time.

Your vision should become stable within the first several weeks after surgery. However, you may experience some small changes (for example, improvement or worsening of your vision). These changes may occur up to six months or more after surgery.

A haze or cloudiness may be seen in the cornea following surgery, but usually does not affect your vision. This haze typically disappears over time, but some patients may continue to experience haze.

IMPORTANT:

Use the anti-inflammatory eye drops and lubricants as directed by your doctor. Your laser vision correction results depend upon your following your doctor's directions.

Questions to Ask Your Doctor

You may want to ask the following questions to help you decide if Custom-CAP™ treatment is right for you:

- What other options are available for correcting my visual difficulties?
- Will I have to limit my activities after surgery, and for how long?
- What are the benefits of Custom-CAP treatment for my amount of nearsightedness, farsightedness, and/or astigmatism, and my decentered treatment?
- What vision can I expect in the first few months after surgery?
- If Custom-CAP treatment does not correct or improve my vision, what is the possibility that my glasses will need to be stronger than before? Could my need for glasses increase over time?
- Will I be able to wear contact lenses after laser surgery if I need them?
- How is treatment with Custom-CAP likely to affect my need to wear glasses or contact lenses as I get older?
- Will my cornea heal differently if injured after having laser surgery?
- Should I have Custom-CAP surgery on my other eye?
- How long will I have to wait before I can have surgery on my other eye?
- What vision problems might I experience if I have Custom-CAP surgery only on one eye?

Discuss the cost of surgery and follow-up care requirements with your doctor, as laser vision correction is not covered by most health insurance policies.

Self-Test

Are You an Informed and Educated Patient?

Take the test below and see if you can correctly answer these questions after reading this booklet.

	TRUE	FALSE
1. Laser refractive surgery is risk free.	<input type="checkbox"/>	<input type="checkbox"/>
2. Laser surgery is the same as radial keratotomy (RK).	<input type="checkbox"/>	<input type="checkbox"/>
3. It doesn't matter if I wear my contact lenses when my doctor told me not to.	<input type="checkbox"/>	<input type="checkbox"/>
4. The laser does all the work; I just have to lie on the chair.	<input type="checkbox"/>	<input type="checkbox"/>
5. After the surgery, there is a good chance that I will be less dependent on eye glasses.	<input type="checkbox"/>	<input type="checkbox"/>
6. I may need reading glasses after laser surgery.	<input type="checkbox"/>	<input type="checkbox"/>
7. There is a risk that I may lose some vision after laser surgery.	<input type="checkbox"/>	<input type="checkbox"/>
8. It doesn't matter if I am pregnant.	<input type="checkbox"/>	<input type="checkbox"/>
9. If I have an autoimmune disease, I am still a good candidate for laser surgery.	<input type="checkbox"/>	<input type="checkbox"/>

Answers to SELF-TEST are found on page 12.

Summary of Important Information

- You are NOT a candidate for Custom-CAP™ treatment if you have NOT already had a laser vision correction procedure.
- Laser vision surgery is a permanent operation to the cornea and is irreversible.
- Laser surgery using the Custom-CAP™ Method is to be used to assist patients who have already had laser refractive surgery and are experiencing difficulties with their surgical result.
- Laser vision correction may not eliminate the need for reading glasses, even if you never have worn them before.
- Your vision must be stable for at least one year before laser vision correction. You will need written evidence that your nearsightedness, farsightedness, and/or astigmatism has changed less than 0.50 diopters.
- Pregnant and nursing women should wait until they are not nursing and not pregnant to have the surgery.
- You are not a good candidate if you have degenerative or autoimmune diseases, or have a condition that makes wound healing difficult.
- Laser vision correction may result in some discomfort. The surgery is not risk-free. Please read this entire booklet, especially the sections on Benefits and Risks before you agree to the surgery.

Summary of Important Information (continued)

- PRK and LASIK are not laser versions of radial keratotomy (RK) or automated lamellar keratectomy (ALK). PRK and LASIK are completely different from RK and ALK.
- Alternatives to PRK and LASIK include, but are not limited to, glasses, contact lenses, RK, and ALK.
- Some people, such as military pilots, have job-related vision requirements that cannot be met by having RK, ALK, PRK, or LASIK.
- Before considering laser vision correction you should:
 - a. Have a complete eye examination.
 - b. Talk with one or more eye care professionals about the potential benefits of PRK or LASIK surgery, and the complications, risks, and time required for healing.

Answers to Self-Test Questions:

1. False (see Risks on page 4); 2. False (see What are PRK and LASIK? on page 2); 3. False (see Before The Surgery on page 6); 4. False (see The Day of Surgery on page 6); 5. True (see Benefits on page 3); 6. True (see What are PRK and LASIK? on page 2); 7. True (see Risks on page 4); 8. False (see Contraindications on page 4); 9. False (see Contraindications on page 4).

Glossary

This section contains definitions of terms used in this information booklet. Please discuss with your doctor any questions you may have about these terms.

Antibiotic Medication: a drug used to treat or prevent infection.

Anti-inflammatory Medication: a drug that reduces redness and swelling associated with inflammation. May be a corticosteroid, or a nonsteroidal anti-inflammatory drug.

Astigmatism: The cornea and lens focus light rays at multiple points at differing distances from the retina. The multiple focal points result in blurred distance and/or near vision.

Automated Lamellar Keratectomy (ALK): a type of surgery used to correct vision by removing a cap of cornea using a microkeratome (an automated instrument), reshaping or flattening the cap of cornea, and then replacing the cap on the corneal bed.

Cataract: an opacity or clouding of the lens inside the eye that can cause a loss of vision.

Collagen Vascular Disease: a condition that may result in inflammation or swelling of parts of the body, such as muscles, joints, and blood vessels. Examples of this type of disease are lupus and rheumatoid arthritis.

Contraindications: any special condition that results in the treatment being inadvisable.

Cornea: the clear front surface of the eye. Surgery such as PRK and LASIK reshape or flatten this surface to correct vision.

Corneal Epithelium: the top layer of the cornea. The doctor removes this layer during PRK surgery. The epithelium then grows back a few days after PRK surgery.

Corneal Haze: a cloudiness of the cornea that may occur after PRK and LASIK.

Corneal Ulcer: an infection of the cornea that may result in a loss of vision.

Diopter (D): a unit used to measure the amount of myopia, hyperopia, or astigmatism of any eye.

Farsightedness: The cornea and lens focus light rays from near objects beyond the retina, causing images of near objects to appear blurry. Hyperopia is another term for farsightedness.

Glaucoma: a condition usually associated with high eye pressure. This condition results in damage to the nerve at the back of the eye and possible loss of vision.

Halos: circular flares or rings of light that may appear around a headlight or other lighted object.

Herpes Simplex: a type of infection caused by a virus that can recur. This virus typically causes cold sores and/or vesicles to appear on the face or other parts of the body.

Herpes Zoster: a type of infection caused by a virus that can recur. Vesicles typically appear on only one side of the body.

Highly Nearsighted: nearsightedness greater than -6 diopters.

Hyperopia: The cornea and lens focus light rays from near objects beyond the retina, causing images of near objects to appear blurry. Farsightedness is another term for hyperopia.

Immunodeficiency Disease: a condition that alters the body's ability to heal. An example is AIDS.

Intraocular Pressure (IOP): fluid pressure inside the eye. Your doctor measures the pressure inside the eye with a tonometer.

Keratoconus: a condition of the cornea that results in a thinning of the cornea. A change in corneal shape like a cone typically occurs.

LASIK: a type of surgery used to correct vision by raising a flap of cornea using a microkeratome (an automated instrument), then reshaping the cornea underneath using an excimer laser, and then replacing the flap on the corneal bed.

Lens: a structure inside the eye that helps to focus light onto the back of the eye.

Mildly Nearsighted: nearsightedness between -1.0 and -6.0 diopters.

Moderately Farsighted: farsightedness between +1.0 and +6.0 diopters.

Myopia: The cornea and lens focus light rays from distant objects in front of the retina, causing images of distant objects to appear blurry. Nearsightedness is another term for myopia.

Nearsightedness: The cornea and lens focus light rays from distant objects in front of the retina, causing images of distant objects to appear blurry. Myopia is another term for nearsightedness.

Ocular Hypertension: an increase in the pressure inside the eye.

Photorefractive Keratectomy (PRK): a type of surgery used to correct vision by reshaping the cornea using an excimer laser.

Radial Keratotomy (RK): a type of surgery used to correct vision by flattening the cornea with a scalpel.

Re-epithelialization: regrowth of the top layer of the cornea. The epithelium is removed before the PRK treatment and usually grows back within a few days after the treatment.

Refractive Error: parallel light rays are not brought to a sharp focus precisely on the retina, producing a blurred image. Refractive errors can be myopic, astigmatic, or hyperopic.

Regression: a decrease in the amount of vision correction after PRK or LASIK surgery.

Retina: the back surface of the eye. The retina takes focused light and transfers it to the brain.

Patient Assistance Information

Primary Eye Care Professional

Name: _____

Address: _____

Phone: _____

Laser Vision Correction Doctor

Name: _____

Address: _____

Phone: _____

Treatment Location

Name: _____

Address: _____

Phone: _____

Laser Manufacturer:

VISX, Incorporated
3400 Central Expressway
Santa Clara, CA 95051
U.S.A.
Tel: 408.733.2020